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GUIDELINES AND SPECIFICATIONS FOR PREPARING QUALITY ASSURANCE PROGRAM PLANS

QAMS-004/80

Quality Assurance Management Staff
Office of Monitoring Systems and Quality Assurance
Office of Research and Development
United States Environmental Protection Agency

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16. ABSTRACT

This document contains procedures and guidelines for complying with EPA's requirement that States and local jurisdictions submit a QA Program Plan when applying for financial assistance. A QA Program Plan is an orderly assembly of management policies, objectives, principles and procedures by which an agency or laboratory specifies how it intends to produce quality data.

17. KEY WORDS AND DOCUMENT ANALYSIS

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GUIDELINES AND SPECIFICATIONS

FOR

PREPARING QUALITY ASSURANCE PROGRAM PLANS

QAMS-004/80

This document is provided pursuant to 40CFR Part 30 as revised July, 1983. Although the document was prepared for internal Environmental Protection Agency use, it is being made available as a guide for preparing Quality Assurance (QA) program plans. In using this as a model, care should be taken that EPA-specific language is carefully edited to reflect the recipient's own QA program requirements.

TABLE OF CONTENTS

Subject	Page
Introduction	1
Scope	1
Quality Assurance Program Plan Preparation and Responsibility	2
Quality Assurance Program Plan Submission Procedures	2
Quality Assurance Program Plan Review and Approval	2
Quality Assurance Program Plan Content Requirements	3
1.0 Identification of Office, Region, or Laboratory Submitting Quality Assurance Program Plan	3
2.0 Introduction	3
3.0 Quality Assurance Policy Statement	3
4.0 Quality Assurance Management	4
5.0 Personnel Qualifications	7
6.0 Facilities, Equipment, and Services	7
7.0 Data Generation	8
8.0 Data Processing	10
9.0 Data Quality Assessment	11
10.0 Corrective Action	11
11.0 Implementation Requirements and Schedules	12
Specific Guidance	14
Definition of Terms	18

Appendices

A. Administrator's Policy Statement of May 30, 1979

B. Administrator's Memorandum of June 14, 1979

GUIDELINES AND SPECIFICATIONS FOR PREPARING QUALITY ASSURANCE PROGRAM PLANS

INTRODUCTION

Environmental Protection Agency (EPA) policy requires participation by all EPA Regional Offices, Program Offices, EPA Laboratories and States in a centrally-managed Quality Assurance (QA) program (see Appendix A--Administrator's policy statement of May 30, 1979) and includes all monitoring and measurement efforts mandated or supported by EPA through regulations, grants, contracts, or other formalized means not currently covered by regulation (see Appendix B--Administrator's memorandum of June 14, 1979). The responsibility for developing, coordinating, and directing the implementation of this program has been delegated to the Office of Research and Development (ORD) which established the Quality Assurance Management Staff (QAMS) for this purpose.

In this document, we define "quality assurance" and "quality control" as follows:

Quality Assurance - the total integrated program for assuring reliability of monitoring and measurement data.

Quality Control - the routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process.

Accordingly, the QA program plan is a document to be prepared by each Program Office, Regional Office, and Laboratory which includes the overall policies, organization objectives, and functional responsibilities designed to achieve data quality goals for the activities for which the particular organization is responsible.

SCOPE

The Agency QA program encompasses all environmentally-related measurement activities supported or required by EPA. "Environmentally related measurement activities" include all field and laboratory investigations that generate data involving the measurement of chemical, physical, or biological parameters in the environment; determining the presence or absence of pollutants in waste streams; health and ecological effect studies; clinical and epidemiological investigations; engineering and process evaluations; studies involving laboratory simulation of environmental events; and studies or measurements of pollution transport, including diffusion models.

QUALITY ASSURANCE PROGRAM PLAN PREPARATION RESPONSIBILITY

Each Program Office, Regional Office, National Laboratory, State or other organization is responsible for the preparation and implementation of a QA program plan to cover all environmentally-related measurement activities. For administrative purposes, the plan should be issued by the Deputy Assistant Administrator (DAA), Regional Administrator (RA), or National Laboratory Director, or at a similar level of responsibility within States and other organizations. For example, one overall QA program plan would be prepared for the Office of Monitoring Systems and Quality Assurance and a specific QA program plan for each of its two Environmental Monitoring Systems Laboratories and its one Environmental Monitoring and Support Laboratory (see, for example, page 8 of the implementation plan). For States, each State agency carrying out environmentally-related measurements will prepare a QA program plan.

QUALITY ASSURANCE PROGRAM PLAN SUBMISSION PROCEDURES

QA program plans should be submitted through normal channels of authority for review and approval(s) as shown in Figure 1.

Completed EPA QA program plans must be submitted to the Director, Quality Assurance Management Staff (RD-680), Office of Monitoring Systems and Quality Assurance, Office of Research and Development, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. States and other organizations will submit their QA program plans to the appropriate Regional Quality Assurance Management Officer (RQAMO). Any questions concerning the preparation of QA program plans or requests for technical assistance should be directed to QAMS. The Director of QAMS can be reached on (FTS/202) 382-5763. States and other organizations shall direct questions to the appropriate RQAMO.

QUALITY ASSURANCE PROGRAM PLAN REVIEW AND APPROVAL

QA program plans for EPA organizations will be evaluated by QAMS and either approved or returned with explanation and target date for resubmission, in accordance with QAMS Standard Operation Procedure (SOP) Number 1 of May 19, 1980 for the review and approval of QA program plans. The QA program plans for State agencies will be reviewed and approved by the appropriate EPA Region.

Approval of the QA program plans will be based on completeness and appropriateness in covering the elements described in Sections 1 through 11. A basic requirement for each QA program plan is that either it is or can be implemented and that its implementation can be measured relative to program objectives. For the States, the approval and implementation of the State QA program plan will be incorporated into the State-EPA Agreement.

QUALITY ASSURANCE PROGRAM PLAN CONTENT REQUIREMENTS

Sections 1 through 11 below describe the essential elements required in any QA program plan and indicate format to be used. All eleven elements listed must be considered and addressed. Where an item is not relevant, a brief explanation of why it is not relevant must be included. Section 12 provides a list of reference documents that may be used in the preparation of these plans.

1.0 Identification of Office, Region or Laboratory Submitting Quality Assurance Program Plans

Each QA program plan must have a cover sheet (shown on pp. 5 and 6) listing the following information:

- Document Title
- Document Control Number (assigned by the submitting office)
- Unit's Full Name and Address
- Name, Address (if different from above), and Telephone Number of the Individual Responsible for the Unit
- QA Officer
- Plan Coverage shall identify all major organization units which are required to participate in the QA program
- Concurrences must include the QA Officer for the respective organization
- Approval will be by the RA or DDA or Laboratory Director, and the Director of QAMS

2.0 Introduction

In this section, a brief background, purpose, and scope of the QA program is set forth. This section must state the rationale for QA application to monitoring and measurement activities and establish a basis for integrating the mandatory QA initiative into the program plan.

3.0 Quality Assurance Policy Statement

This policy statement provides the framework within which a unit develops and implements its QA program. The policy statement must describe the unit's goals and specify those requirements and activities needed to realize these goals. Paralleling the Administrator's directive of May 30, 1979, the unit's policy statement must emphasize those requirements and activities needed to ensure that all data obtained are of known quality. Policy is to be directed towards a formal commitment of time and resources necessary to ensure that data are as precise and accurate and as complete and representative as required.

The policy statement indicates management's commitment to QA throughout the data generating and processing operations. All reported data must be accompanied by a calculation of precision and accuracy. Where appropriate, a statement on the completeness, representativeness, and comparability is to be included.

4.0 Quality Assurance Management

4.1 Introduction

This section must present the QA management structure of the organization and its relationship to the national program. This section of the plan shows the interrelationships between the functional units and the subunits which generate or manage data. Also, the relationship between the national program managers and the Regions is to be described.

4.2 Assignment of Responsibilities

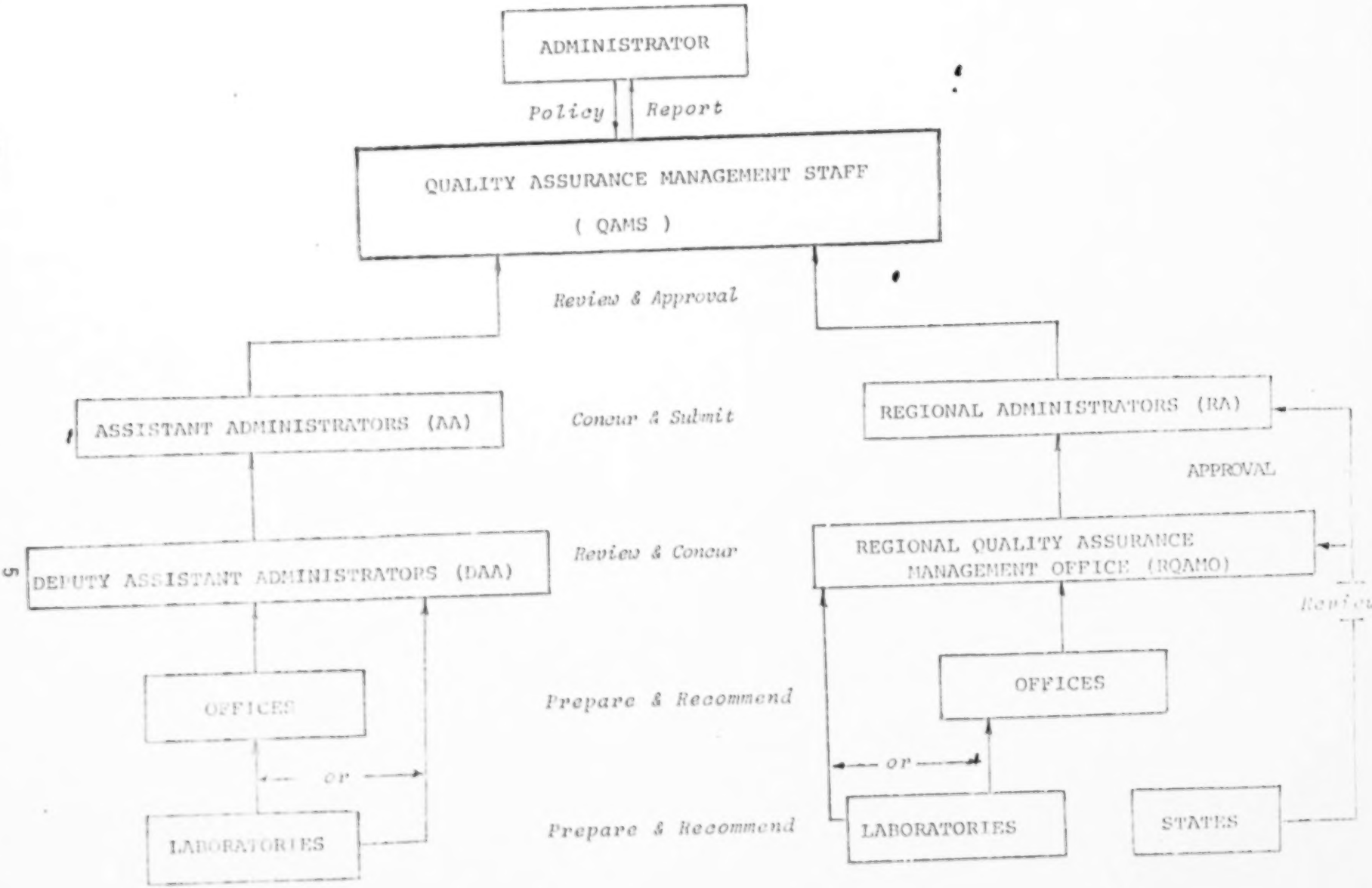
The office with overall QA responsibility for the organization must be identified. The success of the QA program depends on the QA office being organizationally independent of data-generating groups. In EPA, this office must report to at least a Division Director in the Regions and Program Offices, and a comparable level in ORD Laboratories and the National Enforcement Investigations Center-Denver. Quality Control (QC) responsibility within the various organizational subunits should be stated.

The QA responsibilities of national program managers vs. those of the EPA Regions must be described. For example, national program managers will identify the monitoring and measurements which will require QA coverage by Regions or ORD Laboratories, along with minimum specifications and acceptance criteria for the data which are generated. The Regions would be responsible for assuring that QA program and project plans meet these requirements. Both Program Offices and Regions will follow guidance provided by QAMS.

4.3 Communications

The "organizational type" chart should be used to indicate the internal and external flow of QA information and reports. Examples of information and reports are shown in Section 4.5.

The flow of reports and other QA information must be addressed and should specify the following: (1) the responsibility of the QA office; (2) what levels of the unit will receive various reports; (3) how often the reports will be issued; (4) who will review these reports; and (5) who will take follow-up action, if necessary.



PLAN SUBMISSION PROCEDURES

Fig. 1

QUALITY ASSURANCE PROGRAM PLAN IDENTIFICATION FORM

Document Title _____

Document Control Number _____
(Internal Use Only)

Organization Title _____

Address _____

_____

_____

Responsible Official _____ Telephone _____

Title _____

Quality Assurance Officer _____ Telephone _____

Address _____

_____

_____
(If Different From Organization)

Plan Coverage _____

_____

_____

_____

_____

_____

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_____

_____

_____

_____

Concurrences

(1) Name _____

Title _____
(Quality Assurance Officer)

Signature _____ Date _____

(2) Name _____

Title _____
(Responsible Official)

Signature _____ Date _____

Approval for Agency

(1) Name _____

Title _____
(Director, QAMS)

Signature _____ Date _____

Approval for Implementation

(1) Name _____

Title _____
(RA, DAA, or National Laboratory Director)

Signature _____ Date _____

Comments

_____

_____

_____

_____

4.4 Document Control

QA reports and other vital information, plans, and directives are to be maintained under a document control procedure as described in Section 1.4.1 of the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I (EPA-600/9-76-005). Distribution lists of personnel who need to receive QA reports and information should be maintained as part of the document control system.

4.5 QA Program Assessment

This section must describe how an organization will continually review its QA program's benefits and effectiveness.

Each organization is required to conduct periodic assessments of its total QA program. Based on these assessments, a semiannual written status report of QA activities and progress will be forwarded to the QAMS or RQAMO. These QA reports will include such information as:

1. Status of or Changes to QA Program Plans
2. Status of QA Project Plans
3. Measures of Data Quality
4. Significant QA Problems, Accomplishments, and Recommendations
5. Results of Performance Audits
6. Results of Systems Audits
7. Status of QA Requirements for Contracts and Grants
8. Summary of QA Training

5.0 Personnel Qualifications

Each organization must assure that all personnel performing tasks and functions related to data quality have the needed education, training and experience. This includes laboratory technicians, analysts, maintenance technicians, supervisors, principal investigators, statisticians, project officers and QA staff. Personnel qualifications and training needs should be identified.

6.0 Facilities, Equipment, and Services

In this section, the unit's approach to the selection, evaluation and maintenance (both routine and corrective) of its equipment, facilities and services is to be described.

The QA program plan should address general environmental aspects of the facilities and equipment which might impact data quality (temperature, humidity, lighting, dust levels, etc.). It

should also consider maintenance requirements for general utilities and housekeeping services (voltage control, reagent purity, supply of air and water, refrigerators, incubators, laboratory hoods, glove boxes, etc.). In addition, this plan should identify the monitoring and inspection procedures, service manuals, maintenance procedures, and service agreements utilized to maintain performance standards for equipment, including essential ancillary equipment.

7.0 Data Generation

This section of the QA program plan must describe procedures to assure the generation of reliable data by all environmentally-related measurement activities. To assure that all data generated are scientifically valid, defensible, comparable, and of known precision and accuracy, these plans much provide for the use of QA project plans and SOPs.

7.1 Quality Assurance Project Plans

Each QA program plan must identify the types of monitoring and measurement activities for which detailed QA project plans must be developed and followed. QA project plans are to be written for each specific project or each continuing operation by the responsible Program Office, Regional Office, Laboratory, contractor, grantee or other organization. Project plans must contain the following, as applicable:

- Title Page, with provision for approval signatures
- Table of Contents
- Project Description
- Project Organization and Responsibilities
- QA Objectives for Measurement Data, in terms of precision, accuracy, completeness, comparability and representativeness
- Sampling Procedures
- Sample Custody
- Calibration Procedures and References
- Analytical Procedures
- Data Analysis, Validation and Reporting
- Internal QC Checks
- Performance and Systems Audits
- Preventive Maintenance Procedures and Schedules
- Specific Procedures to be used to routinely assess data precision, accuracy, comparability, and representativeness of specific measurement parameters involved
- Corrective Action
- QA Reports to Management

QA project plans should provide for the review of all activities which could directly or indirectly influence data quality and the determination of those operations which must be covered by SOPs. Activities to be reviewed include:

- General Network Design
- Specific Sampling Site Selection
- Sampling and Analytical Methodology
- Probes, Collection Devices, Storage Containers and Sample Additives or Preservatives
- Special Precautions, such as heat, light, reactivity, combustability and holding times
- Federal Reference, Equivalent or Alternate Test Procedures
- Instrument Selection and Use
- Calibration and Standardization
- Preventive and Remedial Maintenance
- Replicate Sampling
- Blind and Spiked Samples
- Colocated Samplers
- QC Procedures, such as intralaboratory and intrafield activities and interlaboratory and interfield activities
- Documentation
- Sample Custody
- Transportation
- Safety
- Data Handling Procedures
- Service Contracts
- Measurement of Precision, Accuracy, Completeness, Representativeness and Comparability
- Document Control

QA project plans must be prepared in document control format, with provision for revision, as needed, and with a record of the official distribution.

7.2 Standard Operating Procedures

SOPs should be developed and used to implement routine QC requirements for all monitoring programs, repetitive tests and measurements and for inspection and maintenance of facilities, equipment and services.

The organization's QA office will assist in the preparation, review, and approval of all SOPs. These SOPs should be prepared in document control format and a record kept of the official distribution. Once prepared, these SOPs need only be included in the QA project plans by reference.

8.0 Data Processing

QA program plans summarize how all aspects of data processing will be managed and separately evaluated in order to characterize and maintain the integrity and quality of the data. Data processing includes collection, validation, storage, transfer and reduction. Those offices operating Automated Data Processing and computer systems for data processing must describe their systems' operations and documentation. Specific instructions should be addressed in QA project plans.

8.1 Collection

The QA project plan must address both manually collected data and computerized data acquisition systems. The internal checks that must be used to avoid errors in the data collection process should be identified.

8.2 Validation

Data validation is defined as the process whereby data are accepted or rejected based on a set of criteria. This aspect of QA involves establishing specified criteria for data validation. The QA project plan must indicate the specified criteria that will be used for data validation.

8.3 Storage

At every stage of data processing at which a permanent collection of data is stored, procedures must be established to ensure data integrity and security. QA project plans must indicate how specific types of data will be stored with respect to media, conditions, location, retention time, and access.

8.4 Transfer

QA project plans will describe procedures which must be used to ensure that data transfer is error-free (or have an admissable error rate), that no information is lost in the transfer, and that the input is completely recoverable from the output. Examples of data transfer are: copying raw data from a notebook onto a data form for keypunching, converting a written data set to punched cards or copying from computer tape to disk. A QA project plan must indicate a minimum number of data transfer steps in the data processing.

8.5 Reduction

Data reduction includes all processes which change either the form of expression or quantity of data values or

numbers of data items. This category includes validation, verification, and statistical and mathematical analysis. It is distinct from data transfer in that it entails a reduction in the size or dimensionality of the data set.

Validation of the data reduction process itself must be addressed (i.e., software validation) appropriate to that level of effort involved. Common to each type of processing is the capability of a reviewer to reliably check the validity of this conversion process against some prescribed methodology.

9.0 Data Quality Assessment

QA program plans must describe how all data generated will be assessed for accuracy, precision, completness, representativeness and comparability. The QA program must require that data be accompanied by a calculation of precision and accuracy. Where appropriate, a statement on the completeness, representativeness, and comparability also should be included.

10.0 Corrective Action

Each QA program plan will include provisions for establishing and maintaining QA reporting or feedback channels to the appropriate management authority to ensure that early and effective corrective action can be taken when data quality falls below required limits. The QA program plans also must include provisions to keep responsible management informed of the performance of all data collection systems and will describe the mechanism(s) to be used when corrective actions are necessary. Corrective action relates to the overall QA management scheme: who is responsible for taking corrective actions; when are corrective actions to be taken; and who follows up to see that corrective actions have been taken and that they have produced the desired results.

Corrective actions will be minimized through the development and implementation of internal controls prior to an adverse program impact. Each measurement system must have limits to establish when corrective action must be taken. A procedure must be established for each measurement system to show what corrective action will be followed when established limits for this procedure have been exceeded. The level within the organization that is responsible for taking corrective action must be specified.

Results from the following QA activities may initiate a corrective action:

A. Performance Audits
B. Systems Audits

C. Interlaboratory/Interfield Comparison Studies
D. Failure to Adhere to a QA Program or Project Plan or to SOPs

11.0 Implementation Requirements and Schedule

The QA program plan must be accompanied by an implementation schedule. An example of the QAMS implementation schedule is shown in the Table on page 13.

IMPLEMENTATION REQUIREMENTS AND SCHEDULE

Requirement	By Whom	Date
Agency QA Policy-General	Administrator	5-30-80
Agency QA Policy-Contracts and Grants	Administrator	6-14-80
Strategy for Developing Mandatory QA Program	ORD/Work Group	2-13-80
Guidelines and Specifications for Preparing QA Program Plans	OMSQA/QAMS	9-20-80
Guidelines for Implementing QA Requirements for Grants	OMSQA/QAMS	2-22-80
Guidelines for Implementing QA Requirements for Contracts	OMSQA/QAMS	2-22-80
Designation of QA Officers*	RAs, DAAs, Labs	3-1-80
Model QA Program Plans (Ambient Air, Water, Region, Laboratory)	ORD POs, ROs	3-24-80
Quality Assurance Clearinghouse	OMSQA/QAMS	5-1-80
Guidelines for Preparing QA Project Plans	ORD POs, ROs	6-30-80
Draft QA Program Plans Submitted	POs, ROs, Labs	6-6-80
Agency QA Report	OMSQA/QAMS	6-2-80
QA Programs/Plans Approved	OMSQA/QAMS	9-15-80
QA Cost Study Report	ROs, ORD Labs	9-15-80
QA Workshops (QAOs, Project Officers, Grants Administrators)	OMSQA/QAMS	To Be Planned
QA Project Plans	POs, ROs, Labs	10-1-80 and Continuing

*Regions and ORD have already designated QA Officers.

SPECIFIC GUIDANCE

Technical details and other information on QA and QC can be obtained from the documents listed below:

EPA-600/9-76-005	Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I--Principles March 1976
EPA-600/4-77-027A	Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II--Ambient Air Specific Methods (especially Section 2.0.9) May 1977
EPA-600/4-77-027B	Quality Assurance Handbook for Air Pollution Measurement Systems, Volume III--Stationary Source Specific Methods August 1977
. . . . .	Traceability Protocol for Establishing True Concentrations of Gases Used for Calibration and Audits of Air Pollution Analyzers Protocol Number 2, June 1978
. . . . .	Transfer Standards for Calibration of Ambient Air Monitoring Analyzers for Ozone June 1978
. . . . .	List of Reference and Equivalent Methods
. . . . .	Criteria, Procedures, and Forms for the Evaluation of Ambient Air Monitoring Programs--Laboratory and Field June 1979
Federal Register Volume 44, 27604	Ambient Air Quality Monitoring, Data Reporting, and Surveillance Provisions May 10, 1979
EPA-600/4-79-019	Handbook for Analytical Quality Control in Water and Wastewater Laboratories March 1979

EPA-600/4-78-017	Procedures for the Evaluation of Environmental Monitoring Laboratories March 1978
EPA-600/4-75-008 NTIS-PB-253258/AS	Interim Radiochemistry Methodology for Drinking Water
EPA-600/8-78-008	Manual for the Interim Certification of Laboratories Involved in Analyzing Public Drinking Water Supplies, Criteria,and Procedures August 1978
EPA-600/8-78-017	Microbiological Methods for Monitoring the Environment December 1978
EPA-600/4-79-202	Methods for Chemical Analysis of Water and Wastes March 1979
EPA-670/4-73-001	Biological Field and Laboratory Methods for Measuring the Quality of Surface Water and Effluents July 1973
EPA-600/7-77-088	Handbook for Analytical Quality Control in Radio-Analytical Laboratories August 1977
EPA-600/4-77-144	Quality Control for Environmental Measurements Using Gamma-Radiospectrometry December 1977
EPA-600/4-78-033 NTIS-PB-286981/AS	Radioactivity Standards Distribution Program, 1978-1979 June 1978
EPA-600/4-78-032 NTIS-PB-284850/AS	Environmental Radioactivity Laboratory Intercomparison Studies Program 1978-1979 June 1978
EPA-600/1-79-008	Manual of Analytical Quality Control for Pesticides and Related Compounds in Human and Environmental Samples

Environmental Toxicology Division, Health Effects Research Laboratory, U.S. EPA, Research Triangle Park, NC	Analysis of Pesticide Residues in Human and Environmental Samples--A Compilation of Methods Selected for Use in Pesticide Montoring Programs

Other guidance documents for the development and implementation of the mandatory QA program are available from QAMS. These include:

QAMS-001/80	Stragegy for the Implementation of the Environmental Protection Agency's Mandatory Quality Assurance Program March 11, 1980
QAMS-002/80	Guidelines and Specifications for Implementing Quality Assurance Requirements for EPA Contracts and Interagency Agreements Involving Environmental Measurements May 19, 1980
QAMS-003/80	Guidelines and Specifications for Implementing Quality Assurance Requirements for EPA Grants and Cooperative Agreements Involving Environmental Measurements September 30, 1980
QAMS-004/80	Guidelines and Specifications for Preparing Quality Assurance Program Plans September 20, 1980
QAMS-005/80	Guidelines and Specifications for Preparing Quality Assurance Project Plans October 17, 1980
. . . . .	A Model Quality Assurance Program Plan for Regional Offices May 1980
. . . . .	A Model Quality Assurance Program Plan for the Office of Air Quality Planning and Standards May 1980

. . . . . A Model Quality Assurance Program Plan for the Office of Water Planning and Standards
May 1980

. . . . . A Model Quality Assurance Program Plan for the Health Effects Research Laboratory-Research Triangle Park, North Carolina
May 1980

. . . . . A Model Quality Assurance Program Plan for the Environmental Research Laboratory-Narragansett
May 1980

DEFINITION OF TERMS

Definitions of key terms used in this guidance material are given below:

AUDIT - a systematic check to determine the quality of operation of some function or activity. Audits may be of two basic types: (1) performance audits in which quantitative or qualitative data are independently obtained for comparison with routinely obtained data in a measurement system, or (2) systems audits of a qualitative nature that consist of an on-site review of a laboratory's quality assurance systems and physical facilities for sampling, calibration and measurement.

CONTRACT - the legal instrument reflecting a relationship between the Federal Government and a State or local government or other recipient: (1) whenever the principal purpose of the instrument is the acquisition, by purchase, lease, or barter of property or services for the direct benefit or use of the Federal Government; or (2) whenever an executive agency determines, in a specific instance, that the use of a type of procurement contract is appropriate.

COOPERATIVE AGREEMENT - the legal instrument reflecting the relationship between the Federal Government and a State or local government or other recipient whenever: (1) the principal purpose of the relationship is the transfer of money, property, services, or anything of value to the State or local government or other recipient to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition, by purchase, lease, or barter of property or services for the direct benefit or use of the Federal Government; and (2) substantial involvement is anticipated between the executive agency acting for the Federal Government and the State and local government or other recipient during performance of the contemplated activity.

DATA QUALITY - the totality of features and characteristics of data that bears on its ability to satisfy a given purpose. The characteristics of major importance are accuracy, precision, completeness, representativeness, and comparability. These characteristics are defined as follows:

- accuracy - the degree of agreement of a measurement (or an average of measurements of the same thing), X, with an accepted reference or true value, T, usually expressed as the difference between the two values, X-T, or the difference as a percentage of the reference or true value, 100 (X-T)/T, and sometimes expressed as a ratio, X/T. Accuracy is a measure of the bias in a system.

- precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions.

  Precision is most desirably expressed in terms of the standard deviation. Various measures of precision exist depending upon the "prescribed similar conditions."

- completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions.

- representativeness - the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or an environmental condition.

- comparability - a measure of the confidence with which one data set can be compared to another.

DATA VALIDATION - a systematic effort to review data to identify any outliers or errors and thereby cause deletion or flagging of suspect values to assure the validity of the data to the user. This "screening" process may be done by manual and/or computer methods, and it may utilize any consistent techniques such as sample limits to screen out impossible values or complicated acceptable relationships of the data with other data.

ENVIRONMENTALLY-RELATED MEASUREMENTS- a term used to describe essentially all field and laboratory investigations that generate data involving the measurement of chemical, physical, or biological parameters in the environment; determining the presence or absence of priority pollutants in waste streams; health and ecological effect studies; clinical and epidemiological investigations; engineering and process evaluations; studies

involving laboratory simulation of environmental events; and studies or measurements of pollutant transport, including diffusion models.

GRANT - the legal instrument reflecting the relationship between the Federal Government and a State or local government or other recipient in which (1) the principal purpose of the relationship is the transfer of money, property, services, or anything of value to the State or local government or other recipient in order to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition, by purchase, lease, or barter, or property or services for the direct benefit or use of the Federal Government; and (2) no substantial involvement is anticipated between the executive agency, acting for the Federal Government, and State or local government or other recipient during performance of the contemplated activity.

GRANTEE - any individual, agency, or entity which has been awarded a grant pursuant to grant regulations.

PERFORMANCE AUDIT- planned independent check of the operation of a measurement system to obtain a quantitative measure of the quality of the data generated. This involves the use of standard reference samples or materials which are certified as to their chemical composition or physical characteristics.

QUALITY ASSURANCE - (1) the total integrated program for assuring the reliability of monitoring and measurement data;

(2) a system for integrating the quality planning, quality assessment, and quality improvement efforts of various groups in an organization to enable operations to meet user requirements at an economical level. In pollution measurement systems, quality assurance is concerned with all of the activities that have an important effect on the quality of the pollution measurements, as well as the establishment of methods and techniques to measure the quality of the pollution measurements. The more authoritative usages differentiate between "quality assurance" and "quality control," where quality control is the system of activities to provide a "quality product" and quality assurance is the "system of activities to provide assurance that the quality control system is performing adequately."

QUALITY ASSURANCE PROGRAM PLAN - an orderly assembly of management policies, objectives, principles, and general procedures by which an agency or laboratory outlines how it intends to produce quality data.

QUALITY ASSURANCE PROJECT PLAN - an orderly assembly of detailed and specific procedures by which an agency or laboratory delineates how it produces quality data for a specific project or measurement method. A given agency or laboratory would have only one quality assurance manual, but would have a quality assurance plan for each of its projects or programs (group of projects using the same measurement methods; for example, a laboratory service group might develop a plan by analytical instrument since the service is provided to a number of projects).

STANDARD OPERATING PROCEDURE - an operation, analysis, or action whose mechanics are thoroughly prescribed and documented and which is commonly accepted as the usual or normal method for performing certain routine or repetitive tasks.

QUALITY CONTROL - the routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process.